

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

UNITED STATES OF AMERICA ex rel.
ROBIN FERRIN

Relator,

v.

Case No.
**FILED UNDER SEAL
PURSUANT TO 31 U.S.C.
§ 3730(b)(2)
DO NOT PUT IN PRESS
BOX OR INTO PACER
SYSTEM**

HCA HEALTH SERVICES OF TENNESSEE, INC.
d/b/a TRISTAR CENTENNIAL MEDICAL CENTER;
HCA HOLDINGS, INC.; TENNESSEE ONCOLOGY, PLLC;
JAMES GRAY, M.D.; D. EDWARD HUNT, M.D.; and
SIRTEX MEDICAL, INC.

Defendants

FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

1. Relator Robin Ferrin brings this action on behalf of the United States against HCA Health Services of Tennessee, Inc. d/b/a Tristar Centennial Medical Center, HCA Holdings, Inc., Tennessee Oncology, PLLC, James Gray, M.D., D. Edward Hunt, M.D., and Sirtex Medical, Inc. for the Defendants' violations of the False Claims Act, 31 U.S.C. § 3729 et seq.

2. Prior to filing this Complaint, pursuant to 31 U.S.C. § 3730(b)(2) and § 3730(e)(4)(B), Relator has provided to the Attorney General of the United States and to the United States Attorney for the Middle District of Tennessee a written disclosure of substantially all material evidence and information she possesses. Because this disclosure statement includes

attorney-client communications and work product of Relators' attorney prepared in anticipation of litigation, and is submitted to the Attorney General and the United States Attorney in their capacity as potential co-counsel in this litigation, Relator understands this disclosure to be confidential.

3. Relator is an "original source" under 31 U.S.C. § 3730(e)(4)(B) because her allegations are based on her personal experiences dealing with the Defendants and while working as an employee of Defendant HCA Health Services of Tennessee, Inc., d/b/a Tristar Centennial Medical Center.

JURISDICTION AND VENUE

4. This action arises under the False Claims Act, 31 U.S.C. § 3729 et seq. This Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732(a) and § 3730(b), as well as 28 U.S.C. § 1345 and § 1331.

5. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because the acts proscribed by 31 U.S.C. § 3729 et seq. and complained of herein took place in this district, and is also proper pursuant to 28 U.S.C. § 1391(b) and (c) because at all relevant times Defendants transacted business in this district.

PARTIES

6. HCA Health Services of Tennessee, Inc. owns, operates and does business as TriStar Centennial Medical Center in Nashville where Relator Robin Ferrin worked as the Manager of Radiation Oncology.

7. HCA Holdings, Inc. is the parent corporation of HCA Health Services of Tennessee, Inc., which does business as TriStar Centennial Medical Center.

8. Robin Ferrin was the Manager of Radiation Oncology at TriStar Centennial

Medical Center from late November 2009 until January 17, 2019. Relator Ferrin lost her job at TriStar due to a reduction in force. She has worked in the health care field continually since 1993, when she graduated from the University of South Carolina. She became a Certified Professional Coder (CPC) in 1999.

9. Tennessee Oncology, PLLC is a Tennessee professional limited liability company based in Nashville with approximately 69 members.

10. James Gray, M.D. is an oncologist who is a member of Tennessee Oncology, PLLC. He practiced at TriStar Centennial Medical Center.

11. D. Edward Hunt, M.D. is an oncologist who is a member of Tennessee Oncology, PLLC. He practiced at TriStar Centennial Medical Center.

12. Sirtex Medical, Inc. is an Australian corporation which does business throughout the United States, including in the Middle District of Tennessee. Its North American office is in Woburn, Massachusetts.

FALSE CLAIMS ACT VIOLATIONS

I. Falsely billing Medicare and other federal health care programs for radiation therapy services as if they were provided under the required “direct supervision” when in fact they were not provided under direct supervision

13. HCA provides radiation therapy services at TriStar Centennial Medical Center in the outpatient radiation oncology department within a hospital setting. These services are required by 42 CFR 410.27(a)(iv)(A) to be furnished under “direct supervision”, which is defined as meaning that the supervising practitioner “must be immediately available to furnish assistance and direction throughout the performance of the procedure.”

14. Section 20.4.4 of Chapter 6 of the Medicare Benefit Policy Manual provides that

“[a]s specified at 42 CFR 410.28(e), payment is allowed under the hospital outpatient prospective payment system for diagnostic services only when those services are furnished under the appropriate level of supervision” This means that the appropriate level of supervision is clearly material to Medicare’s payment decisions for radiation therapy provided to outpatients at TriStar Centennial Medical Center.

15. According to the American Society for Radiation Oncology, “examples of a lack of immediate availability include when a physician is performing another procedure or service that cannot be interrupted, or when a physician is so physically distant on-campus from where the services are being furnished that he or she could not intervene in a timely manner.”

16. Since at least March of 2015, as Relator Ferrin knows from her personal observations and experience, the physicians who were supposed to provide direct supervision over the radiation therapy services provided at TriStar often were actually performing surgeries, and thus were neither immediately available nor interruptible. Moreover, most of the time the physicians who were supposedly providing direct supervision of radiation therapy services provided at TriStar were actually at the off-site Centennial Surgery Center and therefore not even in the same building as the outpatient radiation oncology department.

17. **Exhibit 1** lists examples of patients who received radiation therapy services without the required direct supervision in January 2018 based on Relator’s personal knowledge.

II. Falsely billing Medicare and other federal health care programs for SBRT procedures on patients who were purportedly enrolled in an IRB-approved clinical trial when in truth there was no such actual clinical trial

18. As of January 2014, Medicare covered stereotactic body radiation therapy (SBRT) for low or intermediate risk prostate cancer patients only “when the patient is (A) enrolled in an IRB-approved clinical trial which meets the ‘standards of scientific integrity and

relevance to the Medicare population’ described in IOM 100-03, National Coverage Determinations, Chapter 1, Section 20.32 B.3.a-k; or (B) enrolled in a national or regional clinical registry compliant with the principles established in AHRQ’s ‘Registries for Evaluating Patient Outcomes: A User’s Guide’, such as the Registry for Prostrate Cancer Radiosurgery (RPCR).” **Exhibit 2.** In addition, “[w]hether in a clinical trial or in a national or regional registry, the information about the trial or registry must be included in the clinical record/progress notes.” *Id.*

19. In August 2010, Dr. James Gray of Tennessee Oncology, PLLC was approved to conduct a clinical research study for CyberKnife stereotactic radio surgery in low and intermediate prostate cancer patients. Dr. Gray purported to enroll patients in this study by having them sign consent forms, but stopped collecting the required study data in 2012. Therefore, TriStar’s SBRT claims from 2012 to the present are false claims because they falsely implied that they were done pursuant to an actual clinical trial which recorded data for the trial, when in fact no such data was recorded, as Relator Ferrin knows from her personal observation and investigation.

20. **Exhibit 3** lists some of the patients who enrolled in the SBRT registry study purportedly conducted by Dr. Gray, most of whom were over 65 years old and therefore Medicare eligible. Notably, none of the Patient Information and Informed Consent forms included within **Exhibit 3** are even signed by Dr. Gray or any other “study doctor.”

III. Kickback scheme between HCA, HCA employee Dr. Kennedy, and Tennessee Oncology (Dr. James Gray and Dr. D. Edward Hunt)

21. Tennessee Oncology is the largest oncology group in Tennessee and the co-owner, with HCA, of the CyberKnife machine at TriStar Centennial Medical Center. Tennessee Oncology is a 90 member physician practice, which includes Dr. James Gray and Dr. D. Edward

Hunt, who practiced at TriStar Centennial Medical Center. Dr. Kennedy is an HCA employee working at Tristar Centennial.

22. HCA had a contract with Tennessee Oncology under which Dr. Gray and Dr. Hunt could cover Dr. Kennedy's patients when Dr. Kennedy was away. However, there was no reciprocal agreement permitting Dr. Kennedy to provide direct supervision to Dr. Gray's patients or Dr. Hunt's patients. Yet Dr. Kennedy provided alleged coverage to Dr. Gray and Dr. Hunt¹ while Dr. Gray and Dr. Hunt billed for radiation therapy services at Centennial even though they were not present at Centennial at all.

23. Since at least January of 2014, HCA through Dr. Kennedy provided a valuable service to Tennessee Oncology, without being paid or reimbursed, for the illegal purpose, at least in part, of inducing Dr. Gray and Dr. Hunt to refer their patients to Centennial for radiation therapy services, which Dr. Gray and Dr. Hunt did.

IV. Kickback scheme between HCA and Sirtex Medical, Inc.

24. Sirtex is the manufacturer of the Y90 isotope used in interventional oncology. Since at least 2014, when Dr. Kennedy was hired and started working for HCA on his first Sirtex patient, Sirtex provided free administrative services to HCA, including preauthorization and determination of benefits at TriStar Centennial Medical Center, in order, at least in part, to induce HCA to purchase the Y90 isotope from Sirtex, which HCA did, instead of purchasing the competitor TheraSehere isotope made by BTG Interventional Oncology. The price of the Y90 isotope which HCA pays to Sirtex is approximately \$16,000 per dose. **Exhibit 4.** HCA bills Medicare for more than \$16,000 per dose.

25. Sirtex obtained preauthorization and determination of benefits from each

¹ The patients of Dr. Gray and Dr. Hunt did not consent to being treated by Dr. Kennedy and had no knowledge of any "direct supervision" by Dr. Kennedy.

Medicare carrier needed for HCA to use the Y90 isotope on Dr. Kennedy's patients, including the patients listed in **Exhibit 5**. Sirtex did so without a business agreement contract and without having a HIPAA release for HCA patients. Sirtex's free preauthorization and predetermination of benefits work kept HCA from having to pay an employee to do that work and therefore benefited HCA financially and constituted a financial inducement provided by Sirtex to HCA.

COUNT I

PRESENTING AND CAUSING TO BE PRESENTED FALSE AND FRAUDULENT CLAIMS IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(A) (Defendants HCA Health Services of Tennessee, Inc. d/b/a Tristar Centennial Medical Center and HCA Holdings, Inc.)

26. Relator realleges and incorporates by reference paragraphs 1 through 17.

27. From at least March of 2015 through the present date, Defendants HCA Health Services of Tennessee, Inc. d/b/a Tristar Centennial Medical Center and HCA Holdings, Inc. knowingly presented and caused to be presented claims to the Medicare program and other federal health care programs, specifically including claims for patients who received radiation therapy services in January 2018 listed in **Exhibit 1**, which were false and fraudulent because (A) the radiation therapy services which generated these claims were not provided under the "direct supervision" required for reimbursement by the Medicare program, and (B) these claims for radiation therapy services implicitly, but falsely, represented that these services had been performed under "direct supervision", as is required for Medicare reimbursement.

COUNT II

PRESENTING AND CAUSING TO BE PRESENTED FALSE AND FRAUDULENT CLAIMS IN VIOLATION

OF 31 U.S.C. § 3729(a)(1)(A)

**(Defendants HCA Health Services of Tennessee, Inc.
d/b/a Tristar Centennial Medical Center, HCA
Holdings, Inc., James Gray, M.D., and Tennessee
Oncology, PLLC)**

28. Relator realleges and incorporates by reference paragraphs 1-12 and 18-20.

29. From at least 2012 through the present date, Defendants HCA Health Services of Tennessee, Inc. d/b/a Tristar Centennial Medical Center, HCA Holdings, Inc., James Gray, M.D., and Tennessee Oncology, PLLC knowingly presented and caused to be presented claims to the Medicare program and other federal health care programs, specifically including claims included within **Exhibit 3**, which were false and fraudulent because (A) the stereotactic body radiation therapy (SBRT) services which generated these claims were not provided to low or intermediate risk prostate cancer patients who were either enrolled in an IRB-approved clinical trial or a national or regional clinical registry, as required for reimbursement by the Medicare program, and (B) these claims for SBRT services for low or intermediate risk prostate cancer patients implicitly, but falsely, represented that these services had been performed on patients who were either enrolled in an IRB-approved clinical trial or a national or regional clinical registry.

COUNT III

PRESENTING AND CAUSING TO BE PRESENTED FALSE AND FRAUDULENT CLAIMS IN VIOLATION

OF 31 U.S.C. § 3729(a)(1)(A)

**(Defendants HCA Health Services of Tennessee, Inc.
d/b/a Tristar Centennial Medical Center, HCA Holdings,
Inc., James Gray, M.D., D. Edward Hunt, M.D., and
Tennessee Oncology, PLLC)**

30. Relator realleges and incorporates by reference paragraphs 1-12 and 21-23.

31. From at least 2014, when Dr. Kennedy started working for HCA in the Radiations Oncology department, through the present date, Defendants HCA Health Services of Tennessee, Inc. d/b/a Tristar Centennial Medical Center, HCA Holdings, Inc., James Gray, M.D., D. Edward Hunt, M.D., and Tennessee Oncology, PLLC knowingly presented and caused to be presented claims to the Medicare program and other federal health care programs which were false and fraudulent pursuant to 42 U.S.C. § 1320a-7b(g) because they were the result of referrals made by Dr. Gray and Dr. Hunt as a consequence of HCA/Tristar employee Dr. Kennedy providing uncompensated patient coverage for Dr. Gray and Dr. Hunt for the illegal purpose, at least in part, of inducing Dr. Gray and Dr. Hunt to refer their patients to Centennial for radiation therapy services, which Dr. Gray and Dr. Hunt did.

COUNT IV

**PRESENTING AND CAUSING TO BE PRESENTED
FALSE AND FRAUDULENT CLAIMS IN VIOLATION
OF 31 U.S.C. § 3729(a)(1)(A)
(Defendants HCA Health Services of Tennessee, Inc.
d/b/a Tristar Centennial Medical Center, HCA Holdings,
Inc., and Sirtex Medical, Inc.)**

32. Relator realleges and incorporates by reference paragraphs 1-12 and 24-25.

33. From at least 2014, when Dr. Kennedy was hired and had his first Sirtex patient, through the present date, Defendants HCA Health Services of Tennessee, Inc. d/b/a Tristar Centennial Medical Center and HCA Holdings, Inc. knowingly presented and caused to be presented claims to the Medicare program and other federal health care programs for the Y90 isotope which were false and fraudulent pursuant to 42 U.S.C. § 1320a-7b(g) because they were the result of an illegal kickback arrangement in which Sirtex Medical, Inc. provided Tristar with free preauthorization and predetermination of benefits services, including for the patients listed

in **Exhibit 5**, in return, at least in part, for Tristar purchasing the Y90 isotope from Sirtex Medical, Inc.

PRAYER FOR RELIEF

Wherefore, Relator respectfully requests this Court enter judgment against Defendants and order:

- (a) That the United States be awarded damages in the amount of three times the damages sustained because of the false and fraudulent claims alleged within this Complaint, as the False Claims Act provides;
- (b) That maximum civil penalties be imposed for each and every false and fraudulent claim that the Defendants have presented and caused to be presented;
- (c) That pre and post-judgment interest be awarded, along with reasonable attorneys' fees, costs and expenses which Relator necessarily incurred in bringing and pressing this action;
- (d) That the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act violations for which redress is sought in this Complaint;
- (e) That Relator be awarded the maximum relator share allowed pursuant to the False Claims Act; and
- (f) That the Court award such other and further relief as it deem proper.

DEMAND FOR JURY TRIAL

Relator, on behalf of herself and the United States, demands a jury trial on all claims alleged herein.

Respectfully submitted,


/s/ Kevin J. Darken

Kevin J. Darken
Florida Bar No. 0090956
kdarken@kevindarken.com
iward@kevindarken.com
Kevin J. Darken Law Group, LLC
332 South Plant Avenue
Tampa, Florida 33606
Telephone: (813) 513-4913
Facsimile: (813) 513-4948

/s/ Michael H. Rowan
Tennessee Bar No. 025066
Rowan Law Group
6953 Charlotte Pike Ste 402
Nashville, TN 37209
Telephone:
Fax:
mrowan@rowanwins.com
Counsel for Relator Robin Ferrin

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing False Claims Act Complaint has been furnished by certified mail return receipt requested to: United States Attorney **Donald Q. Cochran**, United States Attorney's Office, 110 9th Avenue South, Suite A-961, Nashville, TN 37203; and to Attorney General **William Barr**, Dept. of Justice, 950 Pennsylvania Ave., N.W., Washington, D.C. 20530 on this 18th day of April, 2019.


Kevin J. Darken